

ANNUAL SYNAR REPORT

42 U.S.C. 300x-26

OMB № 0930-0222

FFY 2024

State: North Carolina

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INTRODUCTION

The Annual Synar Report (ASR) format provides the means for states to comply with the reporting provisions of the Public Health Service Act (42 U.S.C. 300x-26) and the Tobacco Regulation for the Substance Abuse Prevention and Treatment Block Grant (SABG) (45 C.F.R. 96.130 (e)).

How the Synar report helps the Center for Substance Abuse Prevention

In accordance with the tobacco regulations, states are required to provide detailed information on progress made in enforcing youth and young adult tobacco access laws (FFY 2023 Compliance Progress) and future plans to ensure compliance with the Synar requirements to reduce youth and young adult tobacco access rates (FFY 2024 Intended Use Plan). These data are required by 42 U.S.C. 300x-26 and will be used by the Secretary to evaluate state compliance with the statute. Part of the mission of the Center for Substance Abuse Prevention (CSAP) is to assist states¹ by supporting Synar activities and providing technical assistance helpful in determining the type of enforcement measures and control strategies that are most effective. This information is helpful to CSAP in improving technical assistance resources and expertise on enforcement efforts and tobacco control program support activities, including state Synar program support services, through an enhanced technical assistance program involving conferences and workshops, development of training materials and guidance documents, and onsite technical assistance consultation.

How the Synar report can help states

The information gathered for the Synar report can help states describe and analyze substate needs for program enhancements. These data can also be used to report to the state legislature and other state and local organizations on progress made to date in enforcing youth and young adult tobacco access laws when aggregated statistical data from state Synar reports can demonstrate to the Secretary the national progress in reducing youth and young adult tobacco access problems. This information will also provide Congress with a better understanding of state progress in implementing Synar, including state difficulties and successes in enforcing retailer compliance

¹The term “state” is used to refer to all the states and territories required to comply with Synar as part of the Substance Abuse Prevention and Treatment Block Grant Program requirements (42 U.S.C. 300x-64 and 45 C.F.R. 96.121).

with youth and young adult tobacco access laws.

Getting assistance in completing the Synar report

If you have questions about programmatic issues, you may call CSAP's Division of Primary Prevention at (240) 276-2550 and ask for your respective State Project Officer, or contact your State Project Officer directly by telephone or email. If you have questions about fiscal or grants management issues, you may call your Grants Management Specialist in the Office of Financial Resources, Division of Grants Management, at (240) 276-1422.

Where and when to submit the Synar report

The ASR must be received by SAMHSA no later than December 31, 2023 and must be submitted in the format specified by these instructions. Use of the approved format will avoid delays in the review and approval process. The chief executive officer (or an authorized designee) of the applicant organization must sign page one of the ASR certifying that the state has complied with all reporting requirements.

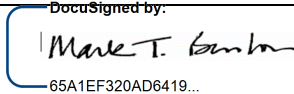
The state must upload one copy of the ASR using the online WebBGAS (Block Grant Application System). In addition, the following items must be uploaded to WebBGAS:

- FFY 2024 Synar Survey Results: States that use the Synar Survey Estimation System (SSES) must upload one copy of *SSES Tables 1–8* (in Excel) to WebBGAS. **Please note that, in the FFY 2024 ASR, SSES will generate Tables 6, 7, and 8, which are based on the optional microdata on product type, retail outlet type, and whether identification was requested. If your state does not submit these optional data, Tables 6, 7, and 8 will be blank. Tables 6, 7, and 8 are generated for the convenience of the state, and states are not required to submit completed versions of Tables 6, 7, or 8.** States that do not use SSES must upload one copy of ASR Forms 1, 4, and 5, and Forms 2 and 3, if applicable, (in Excel), as well as a database with the raw inspection data to WebBGAS.
- Synar Inspection Form: States must upload one blank copy of the inspection form used to record the result of each Synar inspection.
- Synar Inspection Protocol: States must upload a copy of the protocol used to train inspection teams on conducting and reporting the results of the Synar inspections. This document should be different than the Appendix C attached to the Annual Synar Report.
- A scanned copy of the signed Funding Agreements/Certifications

Each state SSA Director has been emailed a login ID and password to log onto the Synar section of the WebBGAS site.

FFY 2024: FUNDING AGREEMENTS/CERTIFICATIONS

The following form must be signed by the Chief Executive Officer or an authorized designee and submitted with this application. Documentation authorizing a designee must be attached to the application.

PUBLIC HEALTH SERVICES ACT AND SYNAR AMENDMENT	
42 U.S.C. 300x-26 requires each state to submit an annual report of its progress in meeting the requirements of the Synar Amendment and its implementing regulation (45 C.F.R. 96.130) to the Secretary of the Department of Health and Human Services. By signing below, the chief executive officer (or an authorized designee) of the applicant organization certifies that the state has complied with these reporting requirements and the certifications as set forth below.	
SYNAR SURVEY SAMPLING METHODOLOGY	
The state certifies that the Synar survey sampling methodology on file with the Center for Substance Abuse Prevention and submitted with the Annual Synar Report for FFY 2024 is up-to-date and approved by the Center for Substance Abuse Prevention.	
SYNAR SURVEY INSPECTION PROTOCOL	
The state certifies that the Synar Survey Inspection Protocol on file with the Center for Substance Abuse Prevention and submitted with the Annual Synar Report for FFY 2024 is up-to-date and approved by the Center for Substance Abuse Prevention.	
State: NC	
Name of Chief Executive Officer or Designee:	<input type="text" value="Mark Benton"/>
Signature of CEO or Designee:	 <small>65A1EF320AD6419...</small>
Title: <input type="text" value="NCDHHS Chief Deputy Secretary for Health"/>	Date Signed: <input type="text" value="12/05/23 12:21 PM EST"/>
If signed by a designee, a copy of the designation must be attached.	

FFY: 2024

State: North Carolina

SECTION I: FFY 2023 (Compliance Progress)

YOUTH AND YOUNG ADULT ACCESS LAWS, ACTIVITIES, AND ENFORCEMENT

42 U.S.C. 300x-26 requires the states to report information regarding the sale/distribution of tobacco products to individuals under age 21.

1. Please indicate any changes or additions to the state tobacco statute(s) relating to youth and young adult access since the last reporting year. If any changes were made to the state law(s) since the last reporting year, please upload a copy of the state law to WebBGAS. (see 42 U.S.C. 300x-26).

a. Has there been a change in the minimum sale age for tobacco products?

Yes No

If Yes, current minimum age: 19 20 21

b. Have there been any changes in state law that impact the state’s protocol for conducting Synar inspections?

Yes No

If Yes, indicate change. (Check all that apply.)

- Changed to require that law enforcement conduct inspections of tobacco outlets
- Changed to make it illegal for youth and young adults to possess, purchase or receive tobacco
- Changed to require ID to purchase tobacco
- Changed definition of tobacco products
- Other change(s) *(Please describe.)* _____

c. Have there been any changes in state law that impact the following?

Licensing of tobacco vendors Yes No

Penalties for sales to minors Yes No

Vending machines Yes No

Added product categories to youth and young adult access law Yes No

2. Describe how the Annual Synar Report (see 45 C.F.R. 96.130(e)) was made public within the state prior to submission of the ASR. (Check all that apply.)

Placed on file for public review

Posted on a state agency Web site *(Please provide exact Web address and the date when the FFY 2024 ASR was posted to this Web address.)*

Web address: <https://www.ncdhhs.gov/divisions/mental-health-developmental-disabilities-and-substance-use-services/reports/annual-synar-report>

Date published: 12/11/23.

- Notice published in a newspaper or newsletter
- Public hearing
- Announced in a news release, a press conference, or discussed in a media interview
- Distributed for review as part of the SUBG application process
- Distributed through the public library system
- Published in an annual register
- Other (*Please describe.*) _____

3. Identify the following agency or agencies (*see 42 U.S.C. 300x-26 and 45 C.F.R. 96.130*).

a. The state agency(ies) designated by the Governor for oversight of the Synar requirements:

NC Department of Health and Human Services, Division of Mental Health
Developmental Disabilities and Substance Use Services.

Has this changed since last year's Annual Synar Report?

Yes No

b. The state agency(ies) responsible for conducting random, unannounced Synar inspections:

NC Department of Public Safety, Alcohol Law Enforcement Division.

Has this changed since last year's Annual Synar Report?

Yes No

c. The state agency(ies) responsible for enforcing youth and young adult tobacco access law(s):

NC Department of Public Safety, Alcohol Law Enforcement Division

Has this changed since last year's Annual Synar Report?

Yes No

4. Identify the following agencies and describe their relationship with the agency responsible for the oversight of the Synar requirements.

a. Identify the state agency responsible for tobacco prevention activities (the agency that receives the Centers for Disease Control and Prevention's National Tobacco Control Program funding).

NC Department of Health and Human Services, Division of Public Health, Tobacco Prevention and Control Branch.

b. Has the responsible agency changed since last year's Annual Synar Report?

Yes No

c. Describe the coordination and collaboration that occur between the agency

responsible for tobacco prevention and the agency responsible for oversight of the Synar requirements. (Check all that apply.) The two agencies

- Are the same
- Have a formal written memorandum of agreement
- Have an informal partnership
- Conduct joint planning activities
- Combine resources
- Have other collaborative arrangement(s) *(Please describe.)* _____
- No relationship

d. Does a state agency contract with the Food and Drug Administration’s Center for Tobacco Products (FDA/CTP) to enforce the youth and young adult access and advertising restrictions in the Family Smoking Prevention and Tobacco Control Act?

- Yes No (if no, go to Question 5)

e. If yes, identify the state agency responsible for enforcing the youth and young adult access and advertising restrictions in the Family Smoking Prevention and Tobacco Control Act (the agency that is under contract to the Food and Drug Administration’s Center for Tobacco Products (FDA/CTP)).

NC Department of Health and Human Services, Division of Mental Health Developmental Disabilities and Substance Use Services.

f. Has the responsible agency changed since last year’s Annual Synar Report?

- Yes No

g. Describe the coordination and collaboration that occur between the agency contracted with the FDA to enforce federal youth and young adult tobacco access laws and the agency responsible for oversight of the Synar requirements. (Check all that apply.) The two agencies:

- Are the same
- Have a formal written memorandum of agreement
- Have an informal partnership
- Conduct joint planning activities
- Combine resources
- Have other collaborative arrangement(s) *(Please describe.)* _____
- No relationship

h. Does the state use data from the FDA enforcement inspections for Synar survey reporting?

- Yes No

5. Please answer the following questions regarding the state’s activities to enforce the state’s youth and young adult access to tobacco law(s) in FFY 2023 (see 42 U.S.C. 300x-26 and 45 C.F.R. 96.130(e)).

a. Which one of the following describes the enforcement of state youth and young adult access to tobacco laws carried out in your state? (Check one category only.)

- Enforcement is conducted exclusively by local law enforcement agencies.
- Enforcement is conducted exclusively by state agency(ies).
- Enforcement is conducted by both local *and* state agencies.

b. The following items concern penalties imposed for all violations of state youth and young adult access to tobacco laws by LOCAL AND/OR STATE LAW ENFORCEMENT AGENCIES (this does not include enforcement of local laws or federal youth and young adult tobacco access laws). Please fill in the number requested. If state law does not allow for an item, please mark “NA” (not applicable). If a response for an item is unknown, please mark “UNK.” The chart must be filled in completely.

PENALTY	OWNERS	CLERKS	TOTAL
Number of <u>citations issued</u>	NA	108	108
Number of <u>finest assessed</u>	UNK	UNK	UNK
Number of <u>permits/licenses suspended</u>	NA		NA
Number of <u>permits/licenses revoked</u>	NA		NA
Other: 1. Required Signage not Posted 2. Receipt of tobacco by person under 18	8		8

Note: Data on the number of citations issued was collected from the Administrative Office of the Courts (AOC) and includes calendar year 2023 only. AOC data can only be obtained for a complete calendar year.

c. Are citations or warnings issued to retailers or clerks who sell tobacco to minors for inspections that are part of the Synar survey?

- Yes** **No**

If “Yes” to 5c, please describe the state’s procedure for minimizing risk of bias to the survey results from retailers alerting each other to the presence of the survey teams:

For the FFY 2024 ASR inspections, ALE issued citations to the clerks that sold to the minors. In addition, merchant education training was offered to the clerk via in-person or online training. During the Synar Recheck, if the retailer sells again, the clerk is issued a citation.

When conducting Synar inspections, ALE uses minors under the age of 18 since the legal age to purchase tobacco is 18 per state statute.

d. Which one of the following best describes the level of enforcement of state youth and young adult access to tobacco laws carried out in your state? (Check one category only.)

- Enforcement is conducted only at those outlets randomly selected for the Synar survey.
- Enforcement is conducted only at a subset of outlets not randomly selected for the Synar survey.
- Enforcement is conducted at a combination of outlets randomly selected for the Synar survey and outlets not randomly selected for the Synar survey.

e. Did every tobacco outlet in the state receive at least one compliance check that included enforcement of the state youth and young adult tobacco access law(s) in the last year?

- Yes No

f. What additional activities are conducted in your state to support enforcement and compliance with state youth and young adult tobacco access law(s)? (Check all that apply and briefly describe each activity in the text boxes below each activity.)

- Merchant education and/or training
Merchant education materials include window decals, and “Check ID” and Retailer Training Cards in both English and Spanish. LME/MCOs and ALE can request these materials from the distribution center and upon receipt, provide them to tobacco retailers as part of their training programs. In total, approximately 22,580 items were distributed to tobacco retailers as part of these training programs. This is a decrease from last year’s distributed amount of 43,000.

There was a decrease in the number of merchant education visits conducted by LME/MCOs. Last year, there were 6,546 merchant education visits conducted in 75 counties. This year there were 3,848 merchant education visits in 81 counties. During these visits, tobacco laws were reviewed, and the outlets received merchant education materials.

ALE’s Online Tobacco Training had 91 employees complete the training representing 38 retailers statewide. This is a decrease from last year’s 1,307 employees participating in the training.

ALE had a slight increase in the number of “Be A Responsible Seller/Server-BARS” onsite trainings conducted from 837 last year to a total of 990 this year. This training focuses on communicating to retail personnel on state laws and penalties for selling tobacco or alcohol to minors. These trainings occurred during regular ALE outlet inspections and the ALE Agent spends approximately 45 minutes reviewing ALE’s scripted PowerPoint training that reviews tobacco laws and the merchant education materials.

- Incentives for merchants who are in compliance (e.g., nonenforcement compliance checks in which compliant retailers are given positive reinforcement and noncompliant retailers are warned about youth and young adult access laws)

- Community education regarding youth and young adult access laws

LME/MCOs conducted three community trainings with local agencies and other partners in their catchment areas that provided education on youth tobacco use, state/federal youth access laws, and how communities can be involved in state efforts to reduce youth access.

- Media use to publicize compliance inspection results

- Community mobilization to increase support for retailer compliance with youth and young adult access laws

The DHHS Training and Technical Assistance Center and the Governor’s Institute hosted virtual workshops for the LME/MCOs. Among other things, the workshops were designed to increase awareness of the state’s RVR, explore solutions to reduce the RVR, solicit LME/MCO assistance, and improve LME/MCO reporting on tobacco related activities. LME/MCOs are required by the Single State Authority (SSA) to provide community mobilization, community and merchant education, public relations, and/or law enforcement activities for a minimum of 48 hours during each 6-month reporting period. Current efforts are being made to see if Synar activities can be increased.

- Other activities (*Please list.*) During the past year, DHHS conducted an ENDS Pilot Study with the assistance of ALE with 400 locations identified for the study. One-half of the retailers selected for the study contained some form of the word “vape” in their retail name such as “Vape House” or “Vapor Outlet,” and the other one-half did not have a form of the word “vape” in their retail name, but were likely to sell vape products, i.e. gas stations. The purpose of the pilot was two-fold: 1) to determine if there is a higher RVR when selling vape products to minors and 2) do vape shops have a higher RVR as a result of less state regulation. For example, grocery stores are regulated by health departments and gas stations are regulated by the Department of Agriculture, whereas “vape shops” receive no other type of regulatory inspection. Analysis continues to be conducted but there is evidence that suggests the RVR when purchasing ENDS products is higher (37% within the ENDS Pilot) than what we observe within the Synar survey, and those retailers with “vape” in their name (receiving less regulatory activity) have a higher RVR between the two groups of the study.

SYNAR SURVEY METHODS AND RESULTS

The following questions pertain to the survey methodology and results of the Synar survey used by the state to meet the requirements of the Synar Regulation in FFY 2023 (see 42 U.S.C. 300x-26 and 45 C.F.R. 96.130).

6. Has the sampling methodology changed from the previous year?

Yes No

The state is required to have an approved up-to-date description of the Synar sampling methodology on file with CSAP. Please submit a copy of your Synar Survey Sampling Methodology (Appendix B). If the sampling methodology changed from the previous reporting year, these changes must be reflected in the methodology submitted.

a. If yes, describe how and when this change was communicated to SAMHSA

7. Please answer the following questions regarding the state's annual random, unannounced inspections of tobacco outlets (see 45 C.F.R. 96.130(d)(2)).

a. Did the state use the optional Synar Survey Estimation System (SSES) to analyze the Synar survey data?

Yes No

If Yes, upload a copy of SSES tables 1–8 (in Excel) to WebBGAS. Then go to Question 8. If No, continue to Question 7b.

8. Did the state's Synar survey use a list frame?

Yes No

If Yes, answer the following questions about its coverage.

a. The calendar year of the latest Sampling frame coverage study: 2022

b. Percent coverage from the latest Sampling frame coverage study: 92.6

c. Was a new study conducted in this reporting period?

Yes No

If Yes, please complete Appendix D (List Sampling Frame Coverage Study) and submit it with the Annual Synar Report.

d. The calendar year of the next coverage study planned: 2025

9. Has the Synar survey inspection protocol changed from the previous year?

Yes No

The state is required to have an approved up-to-date description of the Synar inspection protocol on file with CSAP. Please submit a copy of your Synar Survey Inspection Protocol

(Appendix C). If the inspection protocol changed from the previous year, these changes must be reflected in the protocol submitted.

- a. If Yes, describe how and when this change was communicated to SAMHSA**

- b. Provide the inspection period: From 06/03/2023 to 08/19/2023.**
MM/DD/YY MM/DD/YY

- c. Provide the number of youth and young adult inspectors used in the current inspection year:**

Seventeen (17) youth inspectors were used, however one youth inspector had a birthday and completed inspections under two different ages. Therefore, SSES indicates 18 youth inspectors were used.

NOTE: If the state uses SSES, please ensure that the number reported in 9b matches that reported in SSES Table 4, or explain any difference.

SECTION II: FFY 2024 (Intended Use):

Public Law 42 U.S.C. 300x-26 of the Public Health Service Act and 45 C.F.R. 96.130 (e) (4, 5) require that the states provide information on future plans to ensure compliance with the Synar requirements to reduce youth and young adult tobacco access.

1. In the upcoming year, does the state anticipate any changes in:

- Synar sampling methodology Yes No
 Synar inspection protocol Yes No

If changes are made in either the Synar sampling methodology or the Synar inspection protocol, the state is required to obtain approval from CSAP prior to implementation of the change and file an updated Synar Survey Sampling Methodology (Appendix B) or an updated Synar Survey Inspection Protocol (Appendix C), as appropriate.

2. Please describe the state’s plans to maintain and/or reduce the target rate for Synar inspections to be completed in FFY 2024. Include a brief description of plans for law enforcement efforts to enforce youth and young adult tobacco access laws, activities that support law enforcement efforts to enforce youth and young adult tobacco access laws, and any anticipated changes in youth and young adult tobacco access legislation or regulation in the state.

Activities That Support Law Enforcement Efforts to Enforce Youth Tobacco Access Laws

LME/MCOs and their provider agencies will continue reporting their regional efforts in merchant education, law enforcement-related activities, and media/public relations into the statewide electronic database. This information will be further analyzed to determine if their efforts are effective, which in turn will inform DHHS’s approach and directives on their future activities.

Law Enforcement Efforts to Enforce Youth Tobacco Laws

ALE conducts the Synar survey for DHHS. Established protocols mandate that Synar inspections resulting in a sell or “intent to sell” by the retailer/clerk are offered additional merchant education training, but participation in the training is not mandated. All retailers who sell tobacco during Synar inspections received a Synar Recheck inspection. Citations were issued for violations during the initial Synar inspection and the Synar Recheck to the clerk. In general, there was an overall decrease in merchant education from last year. DHHS will evaluate the occurrence for possible enhancements to increase merchant education.

Anticipated Changes in Youth Tobacco Access Legislation or Regulation

The state does not anticipate any immediate changes to its youth tobacco access laws. Efforts are increasing to implement tobacco licensing and raise the minimum-age for tobacco to twenty-one. Current state law prevents the introduction of 18–20-year-old inspectors to be included in Synar inspections. DHHS will continue to seek any opportunities to address policies that would strengthen the law. The state will continue to be diligent in its efforts to reduce youth tobacco use and access.

3. Describe any challenges the state faces in complying with the Synar regulation. (*Check all that apply and describe each challenge in the text box below it.*)

- Limited resources for law enforcement of youth and young adult access laws
- Limited resources for activities to support enforcement and compliance with youth and young adult tobacco access laws

During the past year, ALE reduced their participation in tobacco enforcement due to competing priorities. While they still conduct the Synar inspections, Synar ReChecks, and enforce the state tobacco youth access law, they have eliminated their participation in the FDA inspection program. ALE did participate in an ENDS Pilot Study which included 400 inspections. Approximately half of the inspections were conducted at retailers whose marquee name included some form of the word “vape” and the other half of the inspections were conducted at retailers that were likely to sell vape products. The study provides valuable information with regards to RVR sales by retailers with “vape” in their name, and when the clerk does not request an ID.

- Limitations in the state youth and young adult tobacco access laws

North Carolina’s minimum-age remains at 18 for tobacco purchases. This creates a challenge to introduce older minors 18-20 into inspections protocols, as it is not a violation of state statutes which prevents enforcement by state enforcement agencies.

- Limited public support for enforcement of youth and young adult tobacco access laws
- Limitations on completeness/accuracy of list of tobacco outlets

North Carolina does not license its tobacco retailers and prior to the FFY 2020 ASR used an area frame for Synar sampling. For the FFY 2020 ASR, a list frame sampling methodology was implemented by combining multiple lists. While the combined list historically achieves the required accuracy and coverage rates, its development does create the challenges associated with combining multiple lists. However, this year’s accuracy rate decreased significantly as a result of retailers that were identified as “out of business” or “no longer sell tobacco.” DHHS is currently analyzing why this occurred and what corrective actions can be taken.

- Limited expertise in survey methodology
- Laws/regulations limiting the use of minors in tobacco inspections
- Difficulties recruiting youth and young adult inspectors
- Issues regarding the balance of inspections conducted by youth inspectors age 15 and under
- Issues regarding the balance of inspections conducted by one gender of youth and young adult inspectors

- Geographic, demographic, and logistical considerations in conducting inspections
- Cultural factors (e.g., language barriers, young people purchasing for their elders)
- Issues regarding sources of tobacco under tribal jurisdiction
- Other challenges: It was determined that there were occasions when inspection protocols for Synar were not followed because of the various types of inspections and protocols completed by the agents. Reinforcement of Synar inspection protocols will be increased through training, follow-up and possible enhancements to the Data Collection Template.

APPENDIXES B & C: FORMS

Instructions

Appendix B (Sampling Design) and Appendix C (Inspection Protocol) are to reflect the state's CSAP-approved sampling design and inspection protocol. These appendixes, therefore, should generally describe the design and protocol and, with the exception of Question #10 of Appendix B, are not to be modified with year-specific information. Please note that any changes to either appendix must receive CSAP's advance, written approval. To facilitate the state's completion of this section, simply cut and paste the previously approved sampling design (Appendix B) and inspection protocol (Appendix C) and respond to Question #10 of Appendix B to provide the requested information about sample size calculations for the Synar survey conducted in FFY 2023.

APPENDIX B: SYNAR SURVEY SAMPLING METHODOLOGY

State: North Carolina
 FFY: 2024

1. What type of sampling frame is used?

- List frame (*Go to Question 2.*)
- Area frame (*Go to Question 3.*)
- List-assisted area frame (*Go to Question 2.*)

2. List all sources of the list frame. Indicate the type of source from the list below. Provide a brief description of the frame source. Explain how the lists are updated (method), including how new outlets are identified and added to the frame. In addition, explain how often the lists are updated (cycle). (After completing this question, go to Question 4.)

Use the corresponding number to indicate Type of Source in the table below.

- 1 – Statewide commercial business list
- 4 – Statewide retail license/permit list
- 2 – Local commercial business list
- 5 – Statewide liquor license/permit list
- 3 – Statewide tobacco license/permit list
- 6 – Other

Name of Frame Source	Type of Source	Description	Updating Method and Cycle
FDA List Frame (Tobacco Inspection Management System (TIMS))	6	Frame file used by FDA to conduct tobacco compliance checks	We will obtain an updated file each year from the FDA, in advance of the annual NC Synar study, to use as the basis for the NC Synar frame. NC will provide updates, based on the annual Synar frame and field study activities, back to the FDA for their use in updating the FDA frame file.
NC Weights and Measures Service Station List	4	List of NC service stations dispensing gasoline. The list is maintained by the State.	An updated version of this file will be obtained each year as part of the frame maintenance process. New and revised service station information will be merged onto the frame file.
Family Dollar and Dollar General stores list	1	Commercial list of all Family General and Dollar General stores in North Carolina	This list will be updated every year as part of the frame maintenance process. New and revised store information will be merged onto the frame file.

3. If an area frame is used, describe how area sampling units are defined and formed.

a. Is any area left out in the formation of the area frame?

- Yes No

If Yes, what percentage of the state’s population is not covered by the area frame?

4. Federal regulation requires that vending machines be inspected as part of the Synar survey. Are vending machines included in the Synar survey?

Yes **No**

If No, please indicate the reason(s) they are not included in the Synar survey. Please check all that apply.

- State law bans vending machines.
- State law bans vending machines from locations accessible to youth and young adults.
- State has a contract with the FDA and is actively enforcing the vending machine requirements of the Family Smoking Prevention and Tobacco Control Act.
- Other (*Please describe.*) _____

If Yes, please indicate how likely it is that vending machines will be sampled.

- Vending machines are sampled separately to ensure vending machines are included in the sample
- Vending machines are sampled together with over-the-counter outlets, so it is possible that no vending machines were sampled, however they are included in the sampling frame and have a non-zero probability of selection
- Other reasons (*Please describe.*) _____

5. Which category below best describes the sample design? (Check only one.)

Census (*STOP HERE: Appendix B is complete.*)

Unstratified statewide sample:

- Simple random sample (*Go to Question 9.*)
- Systematic random sample (*Go to Question 6.*)
- Single-stage cluster sample (*Go to Question 8.*)
- Multistage cluster sample (*Go to Question 8.*)

Stratified sample:

- Simple random sample (*Go to Question 7.*)
- Systematic random sample (*Go to Question 6.*)
- Single-stage cluster sample (*Go to Question 7.*)
- Multistage cluster sample (*Go to Question 7.*)
- Other** (*Please describe and go to Question 9.*) _____

6. Describe the systematic sampling methods. (After completing Question 6, go to Question 7 if stratification is used. Otherwise go to Question 9.)

7. Provide the following information about stratification.

a. Provide a full description of the strata that are created.

Strata will be formed by using the eight districts of the Alcohol Law Enforcement (ALE) branch of the North Carolina State Bureau of Investigation, each formed by an aggregation of several counties. ALE is the State law enforcement agency

responsible for youth tobacco enforcement and will be conducting the fieldwork for the NC Synar studies. These districts are shown in a map below:

ALE District Offices



b. Is clustering used within the stratified sample?

- Yes** (Go to Question 8.)
 No (Go to Question 9.)

8. Provide the following information about clustering.

a. Provide a full description of how clusters are formed. (If multistage clusters are used, give definitions of clusters at each stage.)

Clusters will be individual counties, each randomly selected from within the ALE districts.

b. Specify the sampling method (simple random, systematic, or probability proportional to size sampling) for each stage of sampling and describe how the method(s) is (are) implemented.

At the first stage of sampling, three counties will be randomly selected, with equal probability, from each of the ALE Divisions.

At the second stage of sampling, tobacco outlets from the frame will be randomly selected, with equal probability within the selected county, for each of the counties selected at the first stage.

The allocation of the total sample size to the ALE Districts will be made proportional to the number of outlets on the frame within each district. Within each district, the allocation of sample size to its three selected counties (in stage one) will be made using the relative proportion of outlets within each county.

For instance (numbers are for demonstration purposes only), for District 1 with sampled counties A, B, and C, if County A has 100 outlets on the frame, County B has 200 outlets, while County C has 300 outlets, and the sample size

proportionately allocated to District 1 is 300 outlets, then County A sample size is computed as:

$$\text{Sample Size County A} = 300 \times \frac{100}{(100 + 200 + 300)} = 50 \text{ Tobacco Outlets}$$

The calculation for County B is given by:

$$\text{Sample Size County B} = 300 \times \frac{200}{(100 + 200 + 300)} = 100 \text{ Tobacco Outlets}$$

The calculation for County C is given by:

$$\text{Sample Size County C} = 300 \times \frac{300}{(100 + 200 + 300)} = 150 \text{ Tobacco Outlets}$$

Each of the 24 counties selected from the 8 ALE Districts will be sampled in this manner.

9. Provide the following information about determining the Synar Sample.

a. Was the Synar Survey Estimation System (SSES) used to calculate the sample size?

Yes (Respond to part b.)

No (Respond to part c and Question 10c.)

b. SSES Sample Size Calculator used?

State Level (Respond to Question 10a.)

Stratum Level (Respond to Question 10a and 10b.)

c. Provide the formulas for determining the effective, target, and original outlet sample sizes.

10. Provide the following information about sample size calculations for the Synar survey conducted in FFY 2023

a. If the state uses the sample size formulas embedded in the SSES Sample Size Calculator to calculate the state level sample size, please provide the following information:

Inputs for Effective Sample Size:

RVR: 20.80%

Frame Size: 14,013

Input for Target Sample Size:

Design Effect: 1.0

Inputs for Original Sample Size:

Safety Margin: 25%

Accuracy (Eligibility) Rate: 80%

Completion Rate: 95%

- b. If the state uses the sample size formulas embedded in the SSES Sample Size Calculator to calculate the stratum level sample sizes, please provide the stratum level information:**

Using proportional allocation:

Var. Stratum	Outlet Frame Size	Estimated Outlet Population Size	Number of PSU Clusters Created	Number of PSU Clusters in Sample	Outlet Sample Size	Number of Eligible Outlets in Sample
All Outlets						
1	1,395	1,227	10	3	78	55
2	1,738	957	23	3	95	84
3	1,351	696	9	3	75	59
4	2,271	1,369	11	3	126	103
5	1,772	2,649	9	3	99	77
6	2,454	1,674	9	3	137	104
7	1,907	707	13	3	104	84
8	1,125	356	16	3	64	54
	14,013	9,635	100	24	778	620

- c. If the state does not use the sample size formulas embedded in the SSES Sample Size Calculator, please provide all inputs required to calculate the effective, target, and original sample sizes as indicated in Question 9.**

APPENDIX C: SYNAR SURVEY INSPECTION PROTOCOL SUMMARY

State: North Carolina
 FFY: 2024

Note: Upload to WebBGAS a copy of the Synar inspection form under the heading “Synar Inspection Form” and a copy of the protocol used to train inspection teams on conducting and reporting the results of the Synar inspections under the heading “Synar Inspection Protocol.”

1. How does the state Synar survey protocol address the following?

a. Consummated buy attempts?

- Required
 Permitted under specified circumstances (Describe: _____)
 Not permitted

b. Youth and young adult inspectors to carry ID?

- Required
 Permitted under specified circumstances (Describe: _____)
 Not permitted

c. Adult inspectors to enter the outlet?

- Required
 Permitted under specified circumstances (Describe: Permitted under specified circumstances (Describe: The ALE Agent enters the outlet first to facilitate their assessment of the outlet’s safety. If the ALE Agent detects an unsafe condition before or after entering the outlet, they return to the vehicle before the Youth Inspector leaves the vehicle. Once inside the outlet, the ALE Agent will position themselves to see and hear the transaction. However, there may be occasions when only one mode of observation is possible. The ALE Agent’s position should also facilitate their ability to intercede if a problem arises involving the Youth Inspector.

After the Agent enters the outlet, the Youth Inspector waits 15-20 seconds before exiting the vehicle. This allows the ALE Agent inside the outlet to assess its safety. After 15-20 seconds have elapsed, the Youth Inspector leaves the vehicle at the direction of the second ALE Agent who remains in the vehicle. It is the responsibility of the ALE Agent that remains in the vehicle to monitor (direct line of sight) the Youth Inspector’s safety during their approach to the outlet.

On rare occasions it is permissible for the Youth Inspector to enter the outlet without the presence of the ALE Agent. These occasions usually occur when the outlet is very small, and it is difficult for the ALE Agent and Youth Inspector to enter without appearing to be together.)

- Not permitted

d. Youth and young adult inspectors to be compensated?

- Required
- Permitted under specified circumstances (Describe:)
- Not permitted

2. Identify the agency(ies) or entity(ies) that actually conduct the random, unannounced Synar inspections of tobacco outlets. (Check all that apply.)

- Law enforcement agency(ies)
- State or local government agency(ies) other than law enforcement
- Private contractor(s)
- Other

List the agency name(s): NC Department of Public Safety, Alcohol Law Enforcement Division

3. Are Synar inspections combined with law enforcement efforts (i.e., do law enforcement representatives issue warnings or citations to retailers found in violation of the law at the time of the inspection?)?

- Always
- Usually
- Sometimes
- Rarely
- Never

4. Describe the type of tobacco products that are requested during Synar inspections.

a. What type of tobacco products are requested during the inspection?

- Cigarettes
- Small Cigars
- Cigarillos
- Smokeless Tobacco
- Electronic Cigarettes/Electronic Nicotine Delivery Systems (ENDS)
- Other

b. Describe the protocol for identifying what types of products and what brands of products are requested during an inspection.

Beginning with the FFY 2022 ASR, North Carolina made eligible for inspection all tobacco products. The quantity allotment of each type of tobacco product is pre-determined and assigned within the Data Collection Template. If the assigned tobacco product is not available at the tobacco retailer, the inspection team automatically defaults to cigarettes for the purchase attempt.

The brands of tobacco products requested are determined by: DHHS provides a list of eligible products by category (cigarettes and smokeless tobacco) to ALE. The inspection team chooses the product(s) to be requested from the DHHS list of eligible products at the beginning of the inspection shift and the Youth Inspector requests the selected product(s) for the remainder of the day.

5a. Describe the methods used to recruit, select, and train adult supervisors.

Adult supervisors are ALE Agents and are selected to participate based on the geographic location of the randomly selected outlets and ALE Districts. ALE Agents receive compliance check training for alcohol and tobacco through their agency. In addition, ALE inspection procedures have been amended to include Synar specific inspection protocols.

5b. Describe the methods used to recruit, select, and train youth and young adult inspectors.

Youth inspectors are generally recruited by the ALE Agents within their network of contacts and can include Youth Inspectors from other programs such as FDA inspections. If ALE Agents have trouble recruiting in a specific area, ALE will contact DHHS to assist in recruitment.

Once recruited, the Youth Inspector candidates undergo age testing to ensure their perceived age meets DHHS guidelines. If the Youth Inspector candidate meets the age testing requirements, they are then hired by ALE.

ALE agents provide Synar specific training to the youth inspectors prior to conducting any Synar inspections. The instructions include specific information on the role and responsibilities of the Youth Inspector, followed by role-play exercises covering various scenarios to prepare the Youth Inspector for the types of questions they should expect from retail employees and their correct responses.

6. Are there specific legal or procedural requirements instituted by the state to address the issue of youth and young adult inspectors' immunity when conducting inspections?

a. Legal

Yes No

(If Yes, please describe.)

NCGS 14-313 makes it illegal for a person less than 18 years of age to purchase, acquire or receive tobacco products or cigarette wrapping papers. The two exceptions are if the minor is enlisted by a police or sheriff's department to test compliance or if the minor is working with the NC Department of Health and Human Services to conduct annual, random, unannounced inspections. In both situations prior parental consent is required.

b. Procedural

Yes No

(If Yes, please describe.)

7. Are there specific legal or procedural requirements instituted by the state to address the issue of the safety of youth and young adult inspectors during all aspects of the Synar inspection process?

a. Legal

Yes No

(If Yes, please describe.)

b. Procedural

Yes No

(If Yes, please describe.)

When meeting the Youth Inspector to start the inspection shift, the ALE Agent will direct the Youth Inspector to inform their parent(s) they are with the inspection team. When the inspection shift ends, the inspection team will return the Youth Inspector to a location pre-approved by their parents and direct the Youth Inspector to contact their parent(s) to inform them the inspection shift has ended, and they are no longer with the inspection team. Meeting and dropping off the Youth Inspectors must include the presence of two ALE Agents.

Prior to arriving at a randomly selected outlet, the inspection team will discuss an inspection plan for the outlet. The discussion will include: 1) who will enter the outlet and in what order, 2) what type of tobacco product is to be attempted for purchase, 3) from where the tobacco product purchase attempt is made, e.g., self-service display, over-the-counter or vending machine, and 4) a review of safety measures specific to the outlet.

Upon arriving at each outlet, the driver will attempt to park in a location that is not visible to the clerk. The inspection team should also scan for exterior CCTV cameras which may also alert the clerk.

The safety of the inspection team is DHHS's number one priority, and any outlet randomly selected for inspection can be omitted when there is a safety concern. Any member of the inspection team can deem the location unsafe. A signal for aborting the location due to safety concerns should be established prior to any member of the team entering the location. It is always preferred the Youth Inspector is directly supervised and the ALE Agents maintain a direct line of sight on the Youth Inspector during the entire purchase attempt including: 1) their departure from the vehicle until entering the outlet; 2) while in the outlet; and 3) departure from the outlet and returning to the vehicle. The preferred order to enter the outlet is:

The ALE Agent enters the outlet first to facilitate their assessment of the outlet's safety. If the ALE Agent detects an unsafe condition before or after entering the outlet, they return to the vehicle before the Youth Inspector leaves the vehicle. Once inside the outlet, the ALE Agent will position themselves to see and hear the transaction. However, there may be occasions when only one mode of observation is possible. The ALE Agent's position should also facilitate their ability to intercede if a problem arises involving the Youth Inspector.

After the Agent enters the outlet, the Youth Inspector waits 15-20 seconds before exiting the vehicle. This allows the ALE Agent inside the outlet to assess its safety. After 15-20 seconds have elapsed, the Youth Inspector leaves the vehicle at the direction of the second ALE Agent who remains in the vehicle. It is the responsibility of the ALE Agent that remains in the vehicle to monitor (direct line of sight) the Youth Inspector's safety during their approach to the outlet.

On rare occasions it is permissible for the Youth Inspector to enter the outlet without the presence of the ALE Agent. These occasions usually occur when the

outlet is very small, and it is difficult for the ALE Agent and Youth Inspector to enter without appearing to be together.

Upon the Youth Inspector's departure from the outlet, the ALE agent will also leave the outlet and return to the vehicle but doing so discreetly as to not bring undue attention to the inspection team. This may require a slight delay before the ALE Agent leaves after the Youth Inspector. When all members of the inspection team return to the vehicle, the team will drive to a safe location to complete the inspection form and debrief the inspection.

8. Are there any other legal or procedural requirements the state has regarding how inspections are to be conducted (e.g., age of youth and young adult inspector, time of inspections, training that must occur)?

a. Legal

Yes No

(If Yes, please describe.)

b. Procedural

Yes No

(If Yes, please describe.)

All youth inspectors shall participate in age verification testing before being allowed to participate. Youth Inspectors participating in Synar activities should be age tested every 3-6 months.

A total of twelve (12) State Employees will be used to conduct age testing for each underage person. Ten ALE Supervisors' opinions will be combined with two opinions from DHHS/DMHDDSUS representatives. The opinions of the underage person's age shall be recorded on the form approved and prescribed by DHHS/DMHDDSUS and Division Headquarters. DHHS/DMHDDSUS and ALE should make every effort to secure opinions from varied participants that include differences in age, sex, race, and ethnicity. When twelve (12) opinions have been secured and recorded on the testing form, DHHS/DMHDDSUS and ALE shall average the results and record the average in the appropriate box on the form.

If the age verification testing average age of the underage person is not within the appropriate age parameters, the underage person cannot be utilized in investigations of alcohol sales or tobacco product distribution to underage persons. If the age verification testing average age of the underage person is within the appropriate age parameters, the underage person shall be processed for participation in investigations of alcohol sales or tobacco product distribution to underage persons.

Synar Inspections: No person older than 17 years 10 months of age shall be employed as underage persons.

Compliance employees shall not be used in these operations between the hours of 11 p.m. and 5 a.m. if the underage person has school the next day.

APPENDIX D: LIST SAMPLING FRAME COVERAGE STUDY

(LIST FRAME ONLY)

State: North Carolina
FFY: 2024

1. Calendar year of the coverage study: 2022

2. **a. Unweighted percent coverage found: 90.6%**
 b. Weighted percent coverage found: 92.6%
 c. Number of outlets found through canvassing: 212
 d. Number of outlets matched on the list frame: 192

3. **a. Describe how areas were defined. (e.g., census tracts, counties, etc.)**

Census Tracts

b. Were any areas of the state excluded from sampling?

Yes No

If Yes, please explain.

4. Please answer the following questions about the selection of canvassing areas.

a. Which category below best describes the sample design? (Check only one.)

Census (*Go to Question 6.*)

Unstratified statewide sample:

- Simple random sample (*Respond to Part b.*)
 Systematic random sample (*Respond to Part b.*)
 Single-stage cluster sample (*Respond to Parts b and d.*)
 Multistage cluster sample (*Respond to Parts b and d.*)

Stratified sample:

- Simple random sample (*Respond to Parts b and c.*)
 Systematic random sample (*Respond to Parts b and c.*)
 Single-stage cluster sample (*Respond to Parts b, c, and d.*)
 Multistage cluster sample (*Respond to Parts b, c, and d.*)
 Other (*Please describe and respond to Part b.*) _____

b. Describe the sampling methods.

The frame consisted of all 2,672 census tracts in North Carolina, from which a stratified simple random sample of census tracts was selected for conducting the coverage study. Earlier work during a pilot coverage study indicated there could be wide variability in the number of outlets to be found in census tracts. For this reason, a conservative number of census tracts, 24, were

selected to ensure a sufficient number of outlets would be found during the coverage study. Using **Table 1: Sample Size Determination Chart** in Appendix B, on page 11 of the **Guide for a Synar Sampling Frame Coverage Study**, dated January 2006, a sample size of 24 census tracts is expected to provide sufficient precision in the estimate of the coverage rate. This would be true even if the number outlets located per census tract matched the worst case (lowest number of outlets per census tract) for all 24 census tracts in the 2022 sample, an extremely unlikely outcome.

To reduce the level of effort for the study, two strata were formed, one for census tracts with large areas (greater than 24 square miles) which require more canvassing effort. A second stratum was formed representing all other census tracts, with smaller areas, which were expected to require less canvassing effort.

One census tract was selected from the stratum of larger area census tracts, and the remainder of 23 census tracts was selected from the stratum containing the smaller area census tracts, for a total of 24 census tracts selected.

c. Provide a full description of the strata that were created.

Two strata were formed based on the connection between the geographical area of a census tract and the level of effort required to canvass it for tobacco outlets. Larger areas tend to require more effort in canvassing, so fewer outlets were selected from the stratum containing the larger area census tracts.

The larger area stratum was formed by including all census tracts of 25 square miles or greater, of which there were 593 at the time of sampling. The smaller area stratum was formed by including all other census tracts that contained less than 25 square miles, of which there were 2079 at the time of sampling. There were a total of 2672 census tracts in North Carolina at the time of sampling.

d. Provide a full description of how clusters were formed.

No clusters were formed.

5. Were borders of the selected areas clearly identified at the time of canvassing?

Yes No

6. Were all sampled areas visited by canvassing teams?

Yes (*Go to Question 7.*) No (*Respond to Parts a and b.*)

a. Was the subset of areas randomly chosen?

Yes No

b. Describe how the subsample of visited areas was drawn. Include the number of areas sampled and the number of areas canvassed.

7. Were field observers provided with a detailed map of the canvassing areas?

Yes No

If No, describe the canvassing instructions given to the field observers.

8. Were field observers instructed to find all outlets in the assigned area? **Yes** **No***If No, respond to Question 9.**If Yes, describe any instructions given to the field observers to ensure the entire area was canvassed, then go to Question 10.*

Once the sample of census tracts is drawn, the team develops maps to be used for the coverage study field work. To ensure that the maps are at a large enough scale to be readable by the canvassing teams, the census tracts are broken up into their constituent census block groups for which maps are created. Driving directions are created for each census block group map, and the map is marked accordingly with these directions. Accommodations are made for the driving directions to overlap between adjoining census block groups within the census tract, to ensure complete coverage. Canvassing is conducted only within the interior of the census tract, as defined by its boundaries. Within the interior of the census tract, canvassing is conducted on both sides of the street, while on the boundaries, canvassing is only conducted on the side of the street that is within the census tract boundary.

Each canvasser team uses the driving instructions marked on the maps and looks for potential outlets to investigate. When a potential tobacco outlet is spotted, the canvasser stops and confirms eligibility by entering the establishment, if needed, to observe that it both sells tobacco products that are included in the North Carolina Synar study, and that it is accessible to minors.

When a tobacco outlet is found, its information will be added to the fieldwork coverage study form maintained by the canvasser. This information includes:

- Census tract ID
- Name of the business
- Address of the business
- Other notes relevant to the outlet

The canvasser also takes a photograph using a cell phone to be used if needed for matching to the frame. Canvassers regularly transmit their completed forms and photographs to North Carolina DHHS to ensure the data is secured for the study.

9. If a full canvassing was not conducted:

- a. **How many predetermined outlets were to be observed in each area? _____**
- b. **What were the starting points for each area? _____**
- c. **Were these starting points randomly chosen?**
 Yes **No**
- d. **Describe the selection of the starting points.**
- e. **Please describe the canvassing instructions given to the field observers, including predetermined routes.**

10. Describe the process field observers used to determine if an outlet sold tobacco.

When a potential tobacco outlet is spotted, the canvasser stops and confirms eligibility by entering the establishment, if it is not obvious from viewing the exterior of the outlet, to observe that it both sells tobacco products that are included in the North Carolina Synar study and is accessible to minors.

11. Please provide the state’s definition of “matches” or “mismatches” to the Synar sampling frame? (i.e., address, business name, business license number, etc.)

Matches are defined as outlets identified during canvassing that had a corresponding business name and address on the list frame. Also, the original field inspection sheet is reviewed to ensure there was not an error in recording the outlets in preparation for matching.

12. Provide the calculation of the weighted percent coverage (if applicable).

Weights were calculated based on the relative sampling rates from the two strata. Details are below:

Stratum 1		Stratum 2					
Not on Frame	On Frame	Not on Frame	On Frame				
			27				
		1	2				
			16				
0	2						
		1	2				
			5				
		2	25				
		2	19				
			8				
		2	10				
		2	18				
		1	6				
			15				
		1	11				
			3				
		8	15				
			8				
0	2	20	190				
	100.0%		90.5%				
Weight	593.0		2079.0				
	593.0		1881.0	2474.00	2672.00	92.6%	Weighted Coverage Rate